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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

RENEE CONTRATTO, Plaintiff(s), v. ETHICON, INC., et al., Defendant(s).	No. C03-3804 MJJ (BZ) **ORDER DENYING DEFENDANTS' MOTION TO UPHOLD CONFIDENTIAL DESIGNATION OF DOCUMENTS**

Now before me is the motion of defendants Ethicon, Inc. ("Ethicon") and Lifecore Biomedical, Inc. ("Lifecore") to uphold the confidential designation of certain documents. The facts underlying this litigation are largely set forth in my November 18, 2004 Order denying defendants' motion for a protective order.

On February 9, 2004, Judge Jenkins signed a stipulated protective order, which, among other things, allowed defendants to designate certain documents as confidential.[1]

[1] The stipulated protective order provides that "defendants may designate as 'Confidential' such portions of deposition transcripts of current and former employees, consultants or experts of defendants or experts of plaintiff,

The Protective Order also stated that "Any items designated as containing confidential information shall be properly subject to protection under the Federal Rules of Civil Procedure, Rule 26(c) and designating parties shall not designate any discovery material as 'CONFIDENTIAL' without first making a good faith determination that such protection is warranted." Stipulated Protective Order at 2:2-6. During pretrial discovery, defendants designated all but a few hundred of the three to four hundred thousand documents they produced as confidential. Pursuant to the protective order, plaintiff objected to the confidential designation of these documents, and specifically identified fourteen documents which she believed should not have been designated confidential. The parties were unable to informally resolve their dispute, and defendants timely filed a motion with this Court, requesting that the Court uphold the confidential designation of thirteen of the documents that plaintiff had identified.[2]

The confidentiality of the documents at issue is governed by Rule 26(c). The Protective Order provides that "Any items designated as containing confidential information shall properly be subject to protection under the Federal Rules of

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discovery responses of defendants, including interrogatory answers, responses to requests for admission, etc., expert reports and any documents, data or other materials produced by defendants which contain information in the following categories: trade secrets, confidential research, development, commercial or financial information (hereinafter 'confidential information')." Stipulated Protective Order 1:24-2:2.

[2] While plaintiff asserts that she objected to the designation of fourteen documents, defendants have submitted only thirteen documents, which they contend are at issue. Rolbin Decl. ¶X, Exs. B-N.

Civil Procedure, Rule 26(c)." Stipulated Protective Order at 2:2-4. "It is well-established that the fruits of pretrial discovery are, in the absence of a court order to the contrary, presumptively public." Phillips v. Gen. Motors, 307 F.3d 1206, 1210 (9th Cir. 2002). When a party makes a motion asserting good cause for a protective order pursuant to Rule 26(c), "the court in which the action is pending may make any order which justice requires to protect a party or person from annoyance, embarrassment, oppression, or undue expense or burden, including . . . that a trade secret or other confidential research, development, or commercial information not be revealed or be revealed only in a designated way."[3] Fed. R. Civ. P. 26(c). Under Rule 26(c), "the party asserting good cause bears the burden, for each particular document it seeks to protect, of showing that specific prejudice or harm will result if no protective order is granted." Foltz v. State Farm Mut. Aut. Ins. Co., 331 F3d 1122, 1130 (9th Cir. 2003)(citing Phillips, 307 F.3d at 1210-11; Beckman Indus., Inc. v. Int'l Ins. Co., 966 F.2d 470, 476 (9th Cir. 1992); Deford v. Schmid Prods. Co., 120 F.R.D. 647, 653 (D. Md. 1987)). "Where a business is the party seeking protection,

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[3] The Ninth Circuit has yet to define the term "trade secret" as it appears in Rule 26(c). Defendants have proffered two definitions. The first is found in 21 C.F.R. § 20.61, and applies to a Freedom of Information Act ("FOIA") request to the FDA. See 21 C.F.R. 20.61; Freedom of Information Regulations, 59 F.R. 531 (January 5, 1994). The second is found in section 3426.1 of the California Civil Code, which defines "trade secret" for purposes of the tort of misappropriation. It does not necessarily follow that a definition of information which cannot be appropriated under state law, or which need not be disclosed under a FOIA request, is the same as the definition for purposes of a protective order under Rule 26(c).

it will have to show that disclosure would cause significant harm to its competitive and financial position. That showing requires specific demonstrations of fact, supported where possible by affidavits and concrete examples, rather than broad, conclusory allegations of harm." Deford, 120 F.R.D. at 653. "[B]road allegations of harm, unsubstantiated by specific examples or articulated reasoning do not satisfy the Rule 26(c) test." Beckman, 966 F.2d at 476. If the court finds that defendants have met their burden to show particularized harm will result from disclosure of the information to the public, the court must then balance the public and private interests to decide whether protection is warranted.[4] Phillips, 307 F.3d at 1211. A judge has broad discretion "to decide when a protective order is appropriate and what degree of protection is required." Id. (citing Seattle Times Co. v. Rhinehart, 467 U.S. 20, 36 (1984)).

As an initial matter, defendants misstate their burden. Defendants contend that once documents are produced pursuant

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[4] In balancing the public and private interests, courts have looked to the following factors: (1) whether disclosure will violate any privacy interests; (2) whether the information is being sought for a legitimate purpose or for an improper purpose; (3) whether disclosure of the information will cause a party embarrassment; (4) whether confidentiality is being sought over information important to public health and safety; (5) whether the sharing of information among litigants will promote fairness and efficiency; (6) whether a party benefitting from the order of confidentiality is a public entity or official; and (7) whether the case involves issues important to the public. Glenmede Trust Co. v. Thompson, 56 F.3d 476, 483 (3d Cir. 1995), *cited with approval in* Phillips, 307 F.3d at 1211-12. Because I find that defendants have not established that the documents at issue are worthy of protection under Rule 26(c), I do not reach plaintiff's argument that the balance of interests favors disclosure.

to a stipulated protective order they have a right to have the "stipulation enforced to protect documents already produced in reliance on the stipulation," and that "it is the plaintiff's burden to show good cause why the documents should be de-designated." Defs.' Mem. of P. & A. in Support of Motion to Uphold Confidential Designation of Certain Documents ("Defs.' Mem. of P. & A.") at 1:9-11, 2:9-10 . Foltz is clear. Defendants must first show "for each particular document it seeks to protect . . . that specific prejudice or harm will result if no protective order is granted." Foltz, 331 F.3d at 1130. "A party who has never made a 'good cause' showing under Rule 26(c) justifying initial protection of disputed documents may not rely solely on the protective order to justify refusal when there is a reasonable request for disclosure." Verizon California, Inc. v. Ronald A. Katz Tech. Licensing, L.P., 214 F.R.D. 583, 586 (C.D. Cal. 2003)(citing Beckman, 966 F.2d at 476; Olympic Ref. Co. v. Carter, 332 F.2d 260, 264-65 (9th Cir. 1964)); see also Foltz, 331 F.3d at 1138. Thus, defendants bear the burden to demonstrate that protection is warranted under Rule 26(c) with respect to each of the thirteen documents at issue.

Second, defendants have not established that "specific prejudice or harm" will result with respect to each of the thirteen documents if they are disclosed. See Foltz, 331 F.3d at 1130. In support of their motion defendants submitted a

single declaration from counsel.[5] See Declaration of Jonathan M. Rolbin in Support of Defendants' Motion to Uphold the Confidential Designation of Certain Documents ("Rolbin Decl."). The declaration fails to explain why the exhibits attached thereto should be protected and fails to identify any specific prejudice or harm that will result from public access to these documents. Defendants' motion similarly fails to address the particular harm that will result from disclosure of each individual document. In their motion, defendants state that "it is plain that the [documents] constitute confidential documents entitled to protection under the terms of the Stipulated Protective Order." Defs.' Mem. of P. & A. at 4:6-7. Yet nowhere is there any factual support for this assertion. Nowhere do they identify any specific secret or otherwise show the specific harm that will result from disclosure of each document. See Foltz, 331 F.3d at 1130.

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[5] With their reply, defendants also submitted a declaration from the Chief Executive Officer of Lifecore Biomedical, Inc., Dennis Allingham. Plaintiff moved to strike the declaration, arguing that defendants' reply should be limited to the facts raised in the moving and opposition papers. Defendants' attempt to introduce new evidence in connection with their reply papers is improper. Exercising my discretion, I grant the motion to strike, in part. To the extent that the declaration introduces new evidence not presented in either the motion or opposition, I did not consider the declaration in making this ruling. See Gold v. Wolpert, 876 F.2d 1327, 1331 n.6 (7th Cir. 1989) ("It is well settled that new arguments cannot be made for the first time in reply. This goes for new facts too."); Payne v. Giant Food, Inc., 346 F. Supp. 2d 15, 21 n.4 (D.D.C. 2004) ("These facts were raised for the first time in his reply . . . petitioners effort to meet his burden comes too late.") (citing U.S. v. Wilson, 240 F.3d 39, 45 (D.C. Cir. 2001)); Schwartz v. Upper Deck Co., 183 F.R.D. 672, 682 (S.D. Cal. 1999) ("It is well accepted that raising of new issues and submission of new facts in [a] reply brief is improper.") (citing Provenz v. Miller, 102 F.3d 1478, 1483 (9th Cir. 1996)).

Defendants' broad allegations of harm with respect to either the documents as a whole, or categories of documents, do not satisfy the standard set forth in Foltz.[6] See id.; Beckman, 966 F.2d at 476.

Finally, even under the generalized showing made by defendants in their motion, protection of the documents under Rule 26(c) is not warranted. "[C]ourts have consistently granted protective orders that prevent disclosure of many types of information, such as letters protected under attorney-client privilege which revealed the weaknesses in a party's position," "medical and psychiatric records," "federal and grand jury secrecy provisions," and "confidential settlement agreements." Phillips, 307 F.3d at 1212 (citations omitted). By contrast, courts have held that documents similar to those sought to be protected in this case were not subject to protection under Rule 26(c). See e.g., Verizon California, Inc. v. Ronald A. Katz Technology Licensing, 214 F.R.D. 583, 586 (C.D. Cal. 2003) (holding that defendants had not established that three memoranda from counsel to the company and a letter regarding an investigation of certain patents were protectable under Rule 26(c)); Grundberg v.

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[6] In their moving papers, defendants also relied upon 21 C.F.R. § 814.9. At the hearing, defendants were unable to explain how this section applied to the documents at issue. Following the hearing, defendants submitted a letter brief stating that they had inadvertently cited to the wrong code section, and pointed the Court to 21 C.F.R. § 801 *et seq.*, 21 C.F.R. § 814.44(d)(1), and 21 C.F.R. § 814.80. These sections generally concern labeling requirements, labeling submissions, and public notice of approval of a PMA by the FDA. They do not purport to protect the documents at issue, nor do they apply to the standard set forth in Foltz.

Upjohn Co., 137 F.R.D. 372 (D. Utah 1991) (holding that defendant drug company failed to establish good cause for maintaining confidential designation of drug experience reports, internal memoranda regarding adverse reactions, a letter from a third party, and other documents related to the drug Halcion); Waelde v. Merck, Sharp & Dohme, 94 F.R.D. 27, 29-30 (E.D. Mich. 1981) (holding that defendant drug company's New Drug Application File was not a trade secret nor did it contain confidential information, and defendant had failed to demonstrate good cause for a protective order). Defendants have failed to demonstrate that the documents at issue here contain either trade secrets or other confidential research, development, or commercial information, let alone identify the specific harm or prejudice that will result from public disclosure of the documents. Defendants' general allegations of harm do not meet the Rule 26(c) standard, and as a result, I find that defendants have not established good cause to uphold the confidential designation of the documents. See Foltz, 331 F.3d at 1130.

In an abundance of caution, given the importance the parties attach to this case, the court has reviewed *in camera* each of the documents in dispute, as well as portions of the transcript of the session at which the parties met and purportedly conferred about whether these documents should have been designated as confidential.[7] Having reviewed these

[7] I have also elected to analyze each document to provide guidance to the Special Master that I am considering appointing to oversee future discovery disputes between the parties.

materials, and having read the generalized showing made by defendants in their motion[8], I conclude that none of the documents defendants seek to protect contain trade secrets or other confidential research, development, or commercial information that Rule 26 protects. For example, the first set of documents, identified as exhibit B to Mr. Rolbin's declaration, contains portions of defendant Lifecore's responses to an FDA deficiency letter which, in effect asks for further information about why Lifecore reached certain conclusions with respect to a patient identified only by number. Rolbin Decl., Ex. B. The response contains mostly medical information about the patient which serves as the basis for the defendant's conclusions, identifies Dr. diZerega as the independent medical review officer who reviewed the data, and then attaches Dr. diZerega's extremely lengthy curriculum vitae. See id. The CV appears to be the sort that Rule 26(a)(2) would require any expert to submit. Nothing in any of these materials appears to be worthy of protection under Rule 26(c).[9]

Exhibit C consists of an internal memorandum prepared by a Dr. Weissberg, Medical Director of defendant Ethicon's

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[8] The absence of a specific showing has made it more difficult to review these documents, many of which are written in technical language.

[9] It is conceivable that within the over 50 pages of this document there might be narrow specific information that would constitute a protectable trade secret but defendants have chosen to seek to protect the entire document on a generalized basis rather than focusing in on any specific information that might be protectable. This is also true with respect to the other documents for which defendants seek protection.

Gynecare's division. Rolbin Decl., Ex. C. The memorandum, in question and answer format, lays out such information as the types of problems that Intergel had experienced, whether the product appears to have been used in conformance with directions, statistical information based on what appears to be historical data about the likelihood of certain events occurring, and an assessment of the consequences of the problems the complainants have faced. Id. This evaluation does not contain any proprietary formulas for the product, ideas for research that might lead to a possible solution to the problems faced, or any other information that appears to the court that might injure defendants if made public.[10]

Exhibit D is a memorandum from Cynthia A. Fink, MPH, of the Weinberger Group, Inc. regarding a review of the June 2, 2000 Intergel PMA Amendment conducted by Robert P. Hirsch, Ph.D. Rolbin Decl., Ex. D. The memorandum summarizes the key points raised during a phone conference with Dr. Hirsch, and generally discusses Dr. Hirsch's evaluation of the PMA Amendment and the issues raised by the FDA with regard to the PMA for Intergel. See id. It also provides advice regarding future discussions with the FDA. See id. It does not appear to contain any secret, proprietary information; nor does the information otherwise appear to be confidential. Exhibit D is

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[10] During the meet and confer session, defendants suggested that some of the sales information might be proprietary. Plaintiff insisted that that information was publically available. As noted in footnote 9, had defendant established that the sales information was proprietary and not publically available, I would have deemed that portion of the document confidential.

not protectable under Rule 26(c).

Exhibit E, an internal Lifecore memorandum, describes a manufacturing investigation of Intergel. Defendants claim that the document contains confidential research and commercial information and that the results and procedure of this investigation have not been revealed to the public and are otherwise valuable to defendants. The memorandum, titled "Intergel Golbule Investigational Update 6-17-03" discusses the presence of small and large globules in several specified lots of Intergel, some of which contained iron. See id., Ex. E. It also explains the use of a filtration system to remove the globules. See id. The documents do not appear to contain secret information, nor does it appear that the public disclosure of the documents would harm defendants. While defendants contended at the hearing that the document contains plans for research, upon further review I have determined that the document only generally summarizes past research performed on the product and does not reveal proprietary formulas for the product or contain confidential research procedures. The document in Exhibit E is not protectable under Rule 26(c).

Exhibit F contains a record of an adverse event experienced by a patient who used Intergel. It does not contain any information which would appear to be useful to a competitor, would otherwise harm defendants, or is otherwise subject to protection under Rule 26(c). The parties shall redact the name of the patient before further disclosing the documents.

Exhibit G contains partial results of animal testing of

actual or potential Intergel ingredients. The final document in Exhibit G is a memorandum, dated April 13, 1993, summarizing the results of the study. Id., Ex. G. Defendants assert that this information could be useful to a competitor seeking to develop a similar product. The documents are more than ten years old and do not contain the type of information which would appear to injure defendants if publicly disclosed.

Exhibit H is a transmittal letter from an Ethicon employee to a third party consultant dated January 12, 1993, transmitting information for an animal study on FeHA to be performed at the Livingston Reproductive Biology Laboratory. Rolbin Decl., Ex. H. The documents also contain handwritten notes related to the study. Id. The model for the study comes from a 1974 publication. Id. Exhibit H is also more than ten years old, and to the best of the court's ability to understand this exhibit, does not appear to contain the type of information which might harm defendants if publicly disclosed. During their meeting, plaintiff asserted that defendants had made publicly available substantial information and data concerning the subject of this test, which defendants did not dispute, and that the data in Exhibit H had not been produced because defendants did not like them. Id., Ex. A; see also Declaration of Stuart C. Talley in Support of Plaintiff's Opposition to Defendants' Motion to Uphold Confidential Designation of Certain Documents ("Talley Decl.") ¶3, Ex. B. Defendants response was simply that the study had not been published and that parts of it were handwritten and should be protected. Rolbin Decl., Ex. A. Nothing in Foltz

supports this proposition. At the hearing, defendants argued that the document contained confidential pre-cursor formulas for Intergel that a competitor could use to develop future products. Defendants did not address this issue in their papers, nor did they seek to redact the particular formulas which appear in the documents. More importantly defendants have not submitted any evidence, in the form of either a declaration or affidavit, demonstrating that this information is proprietary or could otherwise cause them harm. These formulas merely reveal that tests were done involving both low viscosity and high viscosity FeHA, a fact which is generally discussed in a public document drafted by Dr. diZerega. See Talley Decl. ¶3; Ex. P. I find that Exhibit H is not protectable under Rule 26(c).

Exhibit I is a request to the FDA to supplement the information on Intergel's label. It contains revised instructions for Intergel's use and an analysis of complaints received by Lifecore from the time marketing commenced in June 1998 through July 2002. Rolbin Decl., Ex. I. The information contained in the revised instructions for use does not appear to contain trade secrets or confidential information. The documents which analyze the complaints contain a general description of the complaints, statistics, and a summary of the results of animal studies. See id. None of these documents appear to contain trade secrets or otherwise confidential information. In fact, a number of the tables appearing in Exhibit I are apparently publicly available on the FDA's website. See Talley Decl. ¶2, Ex. O.

Exhibit J transmits to the FDA a report of various adverse events related to Intergel that occurred prior to its commercialization in the United States. These reports only generally summarize the complaints made to defendants regarding the use of Intergel in Europe and Asia. Id. They do not reveal any secret information about the product, do not identify the complainant, and do not contain confidential or proprietary information.

Exhibit K contains an amendment to the information submitted to the FDA on February 21, 2003 regarding the Labeling Supplement for Intergel. Rolbin Decl., Ex. K. The amendment includes amended proposed labeling language and a final draft letter introducing the labeling changes to Intergel users. Id. The proposed labeling language is similar to the language in Exhibit I, and does not contain trade secrets or other confidential information. The draft letter is addressed to "Physicians performing abdominal/pelvic surgery" and "Hospital/Ambulatory/Same Day Surgical OR Personnel." Id. It generally explains Ethicon's post-market experience with Intergel, and the need for "repeat surgeries" in "numerous cases." Id. It advises that Intergel "is not indicated for use with laparoscopy." Id. The purpose of the letter is to make clinicians aware of the possibility of adverse events, and to consider it in their patient selection and evaluation of late-onset, post-operative pain. See Id. It also advises "user facilities" and "individual clinicians" of the FDA's mandatory and voluntary reporting requirements. Id. Portions of the document are publicly available.

See Talley Decl., ¶2; Ex. O. Those portions of the document which are not publicly available do not contain what I would consider to be trade secrets or confidential information. Furthermore, the last document in the exhibit is directed toward physicians and facilities that use the product, and the intent in drafting the document appears to have been to eventually disseminate it to Intergel users. Frankly, I am at odds to determine why defendants now believe the document should be designated as confidential.

Exhibits L, M, and N are letters from the FDA to Lifecore. Rolbin Decl., Exs. L,M,N. The letter in Exhibit L states that the FDA has reviewed the PMA and Medical Device Reports ("MDR") for Intergel and concluded that "changes to the labeling for Intergel are required." Id., Ex. L. It also contains a revision to the labeling for Intergel and directs Lifecore to revise the label and submit a PMA Supplement. Id. It does not contain any proprietary formulas for the product, research processes or procedures, or any other information which I would consider to be confidential.

Exhibit M contains a letter from the FDA to the President and CEO of Lifecore, dated April 18, 2002. Rolbin Decl., Ex. M. It addresses the visit of an FDA investigator to Lifecore to determine whether the Lifecore's sponsorship of studies of Intergel complied with applicable FDA regulations. Id. The letter also states that the review of the inspection submitted by the district office revealed deviations from 21 C.F.R. §§ 812 and 814. Id. The deviations include failure to maintain accurate, complete records relating to adverse device effects,

failure to prepare and submit complete, accurate and timely progress and final reports, and failure to include in the PMA an identification, discussion, and analysis of any other data, information, or report relevant to an evaluation of the safety and effectiveness of the device known to defendants from any source, including information derived from investigations other than those proposed in the application. Id. The FDA requests a copy of the corrective actions taken to address these deviations. Id. Although the information contained in this letter may be adverse to defendants' litigation position, it does not contain confidential, proprietary, or otherwise protectable information under Rule 26(c).

The letter in Exhibit N explains that the FDA has reviewed the promotional materials for Intergel, as well as Ethicon's website. Rolbin Decl., Ex. N. The letter addresses information appearing in defendants' promotional materials and on their website which allegedly misrepresent the safety and effectiveness of Intergel and include data inconsistent with the approved PMA. Id. It requests Lifecore to respond to these potential misrepresentations. Id. It does not contain proprietary or confidential information. Defendants' designation of the letter was improper, especially in light of the fact that the content of the letter concerns publicly available information appearing in defendants' promotional materials and on their website.

Having reviewed the thirteen exhibits at issue, I find that they do not contain trade secrets or other confidential research, development, or commercial information. Nor does it

appear that disclosure of these documents would harm defendants. For the foregoing reasons, defendants motion to uphold the confidential designation of the documents is **DENIED.** Plaintiffs request for sanctions is also **DENIED** for failure to comply with Civil Local Rule 7-8.

DATED: February 7, 2005

/s/ Bernard Zimmerman
Bernard Zimmerman
United States Magistrate Judge

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